

REMARKS

Entry of the foregoing and further and favorable consideration of the subject application are respectfully requested and such action is earnestly solicited.

As correctly stated in the Office Action, Claims 1, 3, 5, 16, and 25-28 are pending in the present application. However, contrary to the statement in the Office Action Summary, Claims 1, 3, 5, 16, and 25-28 appear to be rejected. Claims 5, 16, 27, and 28 allegedly stand objected to.

By the present amendment, independent Claims 1 and 25 have been amended to remove the recitation of "curative and prophylactic" from the preamble of these claims. This amendment is not intended to narrow the scope of these claims. Claims 26-28 have been amended to recite the correct claim from which they depend. No new matter has been added.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 3, 5, 16, and 25-28 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled. The Examiner acknowledges that the specification is enabling for the treatment of obesity, but asserts that the specification is not enabling for the curative and prophylactic treatment of obesity. Without conceding to the merits of this rejection, and solely in an effort to expedite prosecution, independent Claims 1 and 25 have been amended to delete "curative and prophylactic" from the preamble. Withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 1, 3, 25, and 26 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Yasuda et al. The Examiner argues that Yasuda et al. disclose a green tea extract prepared by an 80% ethanol extraction. This rejection is respectfully traversed.

Applicants submit herewith a translation of the Yasuda et al. publication. As can be seen from the translation, Yasuda et al. do not disclose which "green tea" is used for their extract. Thus, it cannot be determined with any certainty what type of green tea is used and therefore, the concentration of catechols and catechins that is obtained by such an extract. Therefore, contrary to the Examiner's statement on page 7 of the Office Action, the prior art does not necessarily teach an extract of the same type of *Camellia sinensis* used in the present specification. As Applicants have previously noted, "green tea" is merely a generic term for an extremely broad class of **at least several hundred** plant varieties, all deriving from the *Camellia sinensis* plant.

The Examiner acknowledges that green teas may vary widely with respect to the catechol and caffeine content, parameters that are further varied by the type of extraction solvent used. To meet the limitations of the claims, a green tea extract must contain from 20% to 50% by mass of catechols and from 5% to 10% of caffeine. As Mr. Rombi's Declaration (previously submitted) demonstrated, it is not necessarily so that a particular green tea variety meets the necessary claim limitations when using an 80% ethanol extract. Thus, without further information provided by the Yasuda et al. publication as to which type of green tea was used,

there can be no certainty that the proportions recited in the present claims are achieved by Yasuda et al.

In light of this, the Yasuda publication cannot anticipate the presently claimed invention because it is well established that in order for prior art to anticipate a claimed invention the **inherency must be certain**. *Ex parte Cyba*, 155 USPQ 756 (POBA 1966) (emphasis added). The fact that a prior art article "may" inherently have the characteristics of the claimed product is not sufficient. *Ex parte Skinner*, 2 USPQ2d 1788 (BPAI 1986). Inherency must be a **necessary result** and not merely a possible result. *In re Oelrich*, 212 USPQ 323 (CCPA 1981) (emphasis added). Applicants have established via the Declaration of Max Rombi that the levels of catechols and caffeine in tea extracts widely vary depending on the type of green tea and the extraction solvent used.

Applicants also respectfully disagree that that the term "green tea" is exclusive of the many varieties of *Camellia sinensis*. *Camellia sinensis* certainly is encompassed by the term "green tea" but this term includes the many varieties of *Camellia sinensis*. For example, the Examiner is invited to peruse the website <http://www.specialteas.com/> which offers a large variety of different "green teas" for sale. Thus, it is commonly recognized that the term "green tea" covers many different varieties of tea, including different varieties of *Camellia sinensis*. The Examiner's citation of medical reference books is not conclusive evidence of which "green tea" is used by Yasuda or whether it is the same as the green tea used in the Example in the present application and contains the same content of catechins and caffeine. Applicants note that neither of these medical references conclusively demonstrate that the term "green tea" covers only one type of *Camellia sinensis*.

Yasuda et al. do not cite these medical reference books, which are U.S. publications, whereas Yasuda et al. describe research that took place in Japan. Yasuda et al. likely used a locally available variety of green tea. Moreover, as Yasuda et al. are only interested in the isolation of tea catechins, rather than a synergistic mix of catechins and caffeine, the type of green tea used is probably not terribly important to Yasuda et al.

Contrary to the position taken in the present Office Action, the Examiner still has provided no evidence that the green tea of Yasuda et al., beyond the use of an 80% ethanol extraction, **necessarily** possesses the quantities and proportions required by the presently claimed invention. Applicants have already demonstrated that the 80% ethanol extraction is not a sufficient or accurate indicator of whether the green tea extract of Yasuda et al. contains 20-50% by mass of catechols and 5-10% of caffeine. Yasuda et al. have given no indication of such content nor of the type of green tea used. As previously noted, upon extracting the green tea with 80% ethanol, Yasuda et al. do not analyze the extract at all, but rather immediately chromatograph the extract to obtain fractions containing particular tea catechins. Yasuda et al. add these separately fractionated catechins to chewing gum to determine the effect on halitosis, an effect so remote from the presently claimed invention so as to be completely unrelated. The proportion and amount of caffeine, an essential element of the synergistic combination, is not even mentioned in Yasuda et al. One skilled in the art would not consider Yasuda et al. to disclose a composition with the presently claimed combination of catechols and caffeine. Yasuda et al. fail to disclose synergistic thermogenic and anti-lipase levels of

catechols and caffeine, as in the presently claimed invention. At most, Yasuda et al. disclose that tea catechins, alone, can be used to depress bad breath.

Thus, in light of Applicant's data regarding the variability in the catechol and caffeine content in green teas even with a particular extraction solvent, the failure of Yasuda et al. to indicate the particular type of green tea used, the lack of any analysis by Yasuda et al. on the green tea extract itself, and the failure to disclose whether any caffeine is present, much less the amounts recited in the present claims, there is nothing in the Yasuda et al. publication that is of use to the Examiner in concluding that the present claims are anticipated. Yasuda et al. do not disclose a composition containing a green tea extract with the recited amounts of catechols and caffeine. Moreover, Yasuda et al. do not disclose a composition suitable for oral administration as Yasuda et al. merely describe chewing gum with tea catechins to depress bad breath.

Applicants respectfully submit that the Examiner has not established a *prima facie* case of anticipation based on the Yasuda publication. Withdrawal of this rejection is respectfully requested.

Claims 1, 3, 5, 16, and 25-28 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Dulloo et al. (*Am. J. of Clin. Nutr.* 70:1040-1045 (1999)) in light of Chantre et al. (*Phytomedicine* 9:3-8 (2002)). The Examiner notes that Applicant's foreign priority application cannot be relied upon because a translation of the priority document has not been made of record. This rejection is respectfully traversed.

Applicants submit herewith a verified translation of the priority application. In light of this submission, Applicants respectfully submit that the Dulloo et al. and Chantre et al. publications are not prior art to the present application. Withdrawal of this rejection is respectfully requested.

Conclusions

From the foregoing, further and favorable consideration of the subject application on the merits is respectfully requested and such action is earnestly solicited.

If there are any questions concerning this amendment, or the application in general, the Examiner is respectfully requested to telephone Applicant's undersigned representative so that prosecution may be expedited.

Respectfully submitted,

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